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(54) **A device for transluminal implantation or extraction.**

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US-A- 4 665 918
US-A- 4 732 152

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Description

The present invention relates to a device for transluminal implantation and/or extraction of a substantially tubular, radially expanding stent, according to the first part of claims 1 and 2, respectively, as well as the combination thereof and a stent, according to the first part of claims 13 and 14.

Such a device for transluminal implantation of expanding stents or prostheses is from known US-A-4655 771. Furthermore, US patent 4,732,152 describes a device enabling transluminal implantation of self-expanding stents. The device described in said US patent shows excellent performance in regard to enabling implantation of prostheses or stents in for example blood vessels or other ducts in living animal bodies. However, most implantation devices including that described in US patent 4,732,152 suffer from the serious drawback of not enabling later extraction of an implanted prosthesis or stent. Such extraction of the implanted artifact will sometimes be necessary due to improper location or disturbances created by the presence of the stent.

The present invention has for a main object to provide for an implantation device also enabling easy extraction of an implanted expanding stent when desired.

Another object of the invention is to provide for a device which can be used for implantation as well of a self-expanding stent.

Still another object of the invention is to provide a device enabling proper positioning of such self-expanding stent in connection with its implantation.

The problems are solued by the features of the second part of claims 1 and 2, respectively, and the features of the second part of claims 13 and 14, respectively.

In a preferred embodiment of the device according to the invention gripping handles are provided at the rear or proximal ends of said tubes, said means enabling axial relative movement between said tubes for expanding or folding of said spring members.

To enable proper positioning of the stent in connection with its implantation the central tube may be provided with radial openings preferably at the distal end thereof, through which the site of implantation can be inspected for the purpose of finding the correct location for the stent. It is also possible to make the central tube, at least at the distal end thereof, of a transparent material enabling such inspection.

In the modification of the device according to the invention both the central tube and the exterior tube may be provided with such radial openings at least at the distal ends thereof. Such radial openings are juxtaposed to enable proper inspection in connection with implantation. According to another embodiment said tubes are, at least at the distal ends thereof, made of transparent material to enable proper positioning. According to still another embodiment one of said tubes can be provided with radial openings at the distal end thereof, whereas the other tube can be made of a transparent material.

To enable inspection of the implantation site the device may comprise viewing means such as an endoscope or a telescope positioned inside the central tube and being axially displaceable therein.

To enable access to any location even through tortuous paths to the site of implantation the device according to the invention may be made of a flexible material including also said viewing means if present.

The invention also includes an apparatus for implanting an expandable stent, said apparatus comprising a device as defined above in combination with a stent which is positioned or clamped between said gripping members and said central tube in a contracted state. According to an alternative apparatus this combination is provided with the stent positioned or clamped between said gripping members and said exterior tube in a contracted state. In such apparatuses the stent is preferably of the self-expanding type, and it is particularly preferred to use stents of the type described in US patent No. 4,655,771.

To facilitate the practical handling of the device of the present invention it is preferred to arrange means which prevent relative rotation between the two concentric tubes. Thus, in order to keep the preferred handles enabling axial relative movement of the concentric tubes, i.e. the central tube and the exterior tube, it is important that said handles are aligned under operation, which will be the case if said tubes are prevented from relative rotation. Such means may be constituted by members of the nut and groove type or other suitable arrangement conventional in the art to prevent such relative rotational movement.

The device according to the present invention is useful for implantation or extraction of any radially expanding stent, but it is particularly useful for handling stents of the type of self-expanding stents described in US patent No. 4,655,771, the full disclosure of which is incorporated herein by reference. The advantage of applying the present invention to braided stents of the type disclosed in said US patent primarily lies in the fact that when one end of such stent is subjected to radial compression at several points of its periphery the whole stent without retracting from its annular shape will contract inwardly from the location where the radial forces act. Thus, even if radial forces are applied from the outside to one end of such stent at three different positions evenly distributed around the periphery of the stent there will be no local deformations of the stent at or near said end but the stent will reduce its diameter uniformly and the radial contraction will be transmitted axially along the stent for a substantial part of its length.

The gripping members may have any shape in cross section but they could have a substantially rec-

tangular cross section by having a blade-like shape. They may in one end be attached to the central tube 3 or the exterior tube 5, respectively, in any suitable manner, such as by welding, riveting, soldering or the like. In a preferred embodiment the gripping members are made of a blade shaped spring material and are preformed so that when released from the surrounding exterior tube respectively backwardly extended end section they spring outwardly with their free ends.

The invention will now be described by non-limiting examples with reference to the appended drawings, wherein:

Fig. 1 is a diagrammatic side view, partly in section, of an embodiment of the device of the invention;

Fig. 2 is an enlarged detail of the distal end of the device shown in Fig. 1;

Fig. 3 is a diagrammatic side view of a modification of the instrument shown in Fig. 1 enabling release or extraction of a stent in the opposite direction; and

Figs. 4 to 8 illustrate the procedure for extracting a stent implanted in the urethra of a patient.

The device shown in Fig. 1 is generally designated 1 and is principally constituted by two flexible tubes, one central tube 3 and a surrounding exterior tube 5. Said tubes are substantially coextensive except for the fact that the exterior tube 5 is shorter than central tube 3 by a distance at least corresponding to the length of the stent to be implanted. Each of tubes 3,5 is provided with gripping handles 9 and 11, respectively, attached at the rear ends thereof. Central tube 3 extends through handle 9 of the exterior tube for obvious reasons.

Central tube 3 is, at its distal end, provided with gripping members 21. The number of gripping members 21 is four and they are evenly distributed around the periphery of central tube 3. In the embodiment shown gripping members 21 have a blade-like shape and can be made of a spring steel material. They can be attached to central tube 3 by any suitable means, such as welding, riveting or other way of attachment. In a preferred embodiment of the invention members 21 are cut out of the wall of tube 3 as shown in Fig. 2 and are thus integral with the wall material of said tube. In such embodiment the tube material is suitably a metal or metal alloy having spring properties.

Gripping members 21 are capable of outward springing movement when exterior tube 5 is retracted by bringing handles 9,11 together as shown in Fig. 1. When exterior tube 5 is moved axially forward along central tube 3 spring members 21 will fold and will come to close engagement with the exterior surface of central tube 3.

The device shown in Fig. 1 further comprises a viewing device in the form of a telescope 7 placed inside central tube 3 with its viewing end 8 positioned behind handle 11. For ease of operation handles 9,11 are provided with cavities 13,15 giving a steady grip.

As seen from Fig. 2 central tube 3 is provided with openings 23 suitably positioned for a purpose to be described below.

The device shown in Fig. 1 also includes seal rings 17,19 sealing against the interior tube 3 and the telescope 7, respectively and inlet means 30, to allow a fluid such as water to be injected to the chamber between the telescope and the inner tube 3 allowing a stream of fluid to rinse the distal end of the telescope for better viewing.

The embodiment shown in Fig. 3 enables implantation and extraction of a stent from the opposite direction. In view of the construction of the stent compression thereof results in axial extension. Therefore, one end of the stent when released will obtain exact location in connection with its implantation, whereas its other end will be located in dependence on the ratio between radial contraction and axial expansion. Therefore, the embodiment of Fig. 3 may be useful when the rear end of the stent is to be correctly positioned in an exact location in a lumen.

The device shown in Fig. 3 corresponds in predominant parts to that shown in Fig 1, but the distal end of central tube 3 is provided with an outwardly and backwardly bent end section 25. Moreover, the gripping members 21 are directed rearwardly and attached to the distal end of exterior tube 5 rather than directed forwardly and attached to central tube 3 as shown in Fig. 1. In other respects the device shown in Fig. 3 corresponds closely to that shown in Fig. 1.

In the embodiment shown in Fig. 1 for loading purposes the proximal end of a stent 27 of the type described in US patent 4,655,771 is accomodated beneath gripping members 21, whereafter exterior tube 5 will be axially moved forward so as to move gripping members 21 radially inwardly to compress the proximal end of the stent 27 and keep it firmly in place in a gap against the central tube 3. By further moving the exterior tube 5 axially forward the entire stent 27 will be compressed and kept inside the exterior tube 5. When the loaded device is then inserted into the lumen of a patient, such as into a patient's urethra , not shown in Fig. 1, the telescope 7 can be axially positioned and by viewing through it the insertion can be closely inspected for establishing the proper location where stent 27 is to be released. After reaching the correct location for the distal end of the stent exterior tube 5 is moved back by handle 9. In the position shown in Fig. 1 the proximal end of the stent 27 is released from the gap between the gripping members 22 and the central tube 3. By pulling the entire device slightly backwards in relation to the urethra the entire stent is released and by moving the exterior tube 5 forwardly the gripping members 21 will fold inwardly surrounded by the protecting exterior tube 5 and the device can then be removed from the lumen, such as the urethra with the stent completely surrounded by

exterior tube 5.

With regard to the embodiment shown in Fig. 3 the procedure is similar but when releasing in this case the proximal end of the stent 27 will first expand at the desired position of the vessel not shown in this figure by moving the central tube 3 axially forward and in the position shown in Fig. 3 the stent 27 is released from the gap between the gripping members 21 and the exterior tube 5. The entire device is then pushed forward in relation to the vessel lumen to completely release the stent 27, whereafter the central tube 3 is moved axially backward to the right as seen in Fig. 3 to fold gripping members 21 by the movement of end section 25 against the exterior tube 5 and thus protect the lumen from being affected by the spring members. The device can then be retracted as a whole from the lumen involved.

The procedure used for removing an implanted stent in the urethra 29 will now be described with reference to Figs. 4 to 8.

Fig. 4 shows a stent implanted into a vessel 29 of a patient, e.g. the urethra. The device used from extracting the stent from its location within the urethra is of the type shown in Fig. 1. For extracting however, the exterior tube 5 is first kept in a forward position keeping the spring members 21 in a folded position surrounded by the distal end of the tube 5 thus protecting the lumen of the vessel when moving the device. The encoscope 7 is used for locating the exact position of stent 27 as seen in Fig. 4. After reaching a position somewhat behind stent 27 exterior tube 5 is now moved backwardly, whereby spring members 21 will be released to engage the inside surface of urethra 29 with the distal ends just behind the proximal end of the stent 27. Due to the pressure exerted by spring members 21 onto the interior wall of the lumen, the device can be pushed axially forwardly as seen in Fig. 5, whereby the spring members 21 can slide onto the outside of the proximal end of stent 27. By moving exterior tube 5 to the left spring members 21 will be folded inwardly thus causing contraction of the proximal end of the stent which will be firmly kept in the gap between the spring members and the central tube 3. Further movement of exterior tube 5 to the left will bring the entire stent 27 together with spring members 21 to a position within the protecting exterior tube 5 as illustrated in Fig. 6. The device can now be removed from the urethra of the patient together with stent 27 in its contracted state.

Fig. 7 and Fig. 8 show a detail of the device according to Fig. 4. When removing a self-expanding stent as described in US patent No. 4,655,771, the spring members 21 have only to slide a very short distance, such as a few millimeters onto the interior wall of the lumen, as shown in Fig. 7. Fig. 8 shows how the end of this type of stent when contracted by the tip of the spring members will be elongated axially in direction towards the fixed ends of the spring members thus giving sufficient length of fixation in the gap between the spring members and the interior tube 3 without pushing the device forward.

Also the device of the type shown in Fig. 3 can in a corresponding manner be used as an extractor for implanted stents.

Even if the device is described in relation to the treatment of urethras it is very suitable for the treatment of many other conduits in the human body. The same devices with optical viewing devices can be successfully used for treatments of such vessels as urethra, the trachea, oesophagus and also some blood vessels.

It is to be noted that the invention is not limited to the embodiments described herein. Thus, any suitable materials can be used for different parts of the instrument. It is preferred to use flexible materials to reach difficultly accessible locations of different types of lumen in which case also the viewing devices can be exchanged to or combined with any appropriate imaging device such as X-Ray, ultra-sound. Moreover, the invention is useful not only with regard to the type of stent described in US patent No. 4,655,771, although an excellent performance is obtained in relation to such stent.

Claims

1. A device for transluminal implantation or extraction of a substantially tubular, radially expandable stent (27), the device comprising a central tube (3) having distal and proximal ends, surrounded by an exterior tube (5) axially displaceable relative to the central tube (3), characterized by a plurality of axially extending gripping members (21) attached to the outer surface of said central tube (3) at the distal end thereof, said members being substantially evenly distributed around the periphery of said tube and capable of outward expanding action of their distal ends when retracting said exterior tube (5) from the distal end of said central tube (3), and capable of forming a gap between said members (21) and the central tube (3) when said exterior tube (5) is moved distally in an axial direction of said central tube (3).

2. A device for transluminal implantation or extraction of a substantially tubular, radially expandable stent (27), the device comprising a central tube (3) having proximal and distal ends surrounded by an exterior tube (5) axially displaceable relative to the central tube (3), characterized in that said central tube (3) is provided with a proximally extending end section (25) at the distal end thereof the end section (25) having a larger diameter than the exterior tube (5), and a plurality of axially extending gripping members (21) attached to the

outer surface of said exterior tube (5) at the distal end thereof, said members (21) being substantially evenly distributed around the periphery of said tube (5), and being capable of outward expanding action at their rear ends by moving the central tube (3) with its extending end section (25) axially forwardly, and capable of forming a gap between said members (21) and said exterior tube (5) by moving said central tube (3) proximally in an axial direction of said exterior tube (3).

3. A device according to claim 1 or 2, further comprising handle means (9; 11) at the rear ends of said tubes (3;5) enabling axial relative movement between said tubes for releasing or folding of said gripping members (21).

4. A device according to claim 1, 2 or 3, wherein the number of gripping members (27) is 3 or 4.

5. A device according to claim 1, wherein said central tube (3) is provided with radial openings (23) at the distal end thereof enabling proper positioning of the device under operation.

6. A device according to claim 1, wherein said central tube (3), at least at the distal end thereof, is made of a transparent material enabling proper positioning of the device under operation.

7. A device according to claim 2, wherein one of tubes (3,5) is provided with radial openings at the distal end thereof enabling proper positioning of the device under operation.

8. A device according to claim 2, wherein said tubes (3,5) have radial, juxtaposed openings at the distal end thereof enabling proper positioning of the device under operation.

9. A device according to claim 2, wherein said tubes (3,5), at least at the distal end thereof, are made of transparent material enabling proper positioning of the device under operation.

10. A device according to any of claims 5 to 9, further comprising viewing means such as an endoscope or a telescope (7) positioned inside the central tube (3) and axially displaceable therein.

11. A device according to any preceding claim, wherein the concentric members (3,5,7) are made of flexible materials enabling bending of the device under operation.

12. A device according to any preceding claim, wherein said gripping members are constituted by springing members (21) capable of outward springing action when released.

13. The combination of the device according to claim 1 and a substantially tubular, radially expandable stent (27), characterized in that said stent (27) is positionable between said gripping members (21) and said central tube (3) is in a contracted state.

14. The combination of the device according to claim 2 and a substantially tubular, radially expandable stent, characterized in that said stent (27) is positionable between said gripping members (21) and said exterior tube (5) is in a contracted state.

15. The combination according to claim 13 or 14, wherein said stent (27) is of the self-expanding type.

Patentansprüche

1. Vorrichtung zur transluminalen Implantation oder Extraktion eines im wesentlichen rohrförmigen, radial erweiterbaren Stents (27), wobei die Vorrichtung ein Mittelrohr (3) mit einem nahen und fernen Ende aufweist, das durch ein Außenrohr (5) eingefaßt ist, das axial bezüglich des Mittelrohrs (3) verschiebbar ist, gekennzeichnet durch eine Vielzahl von sich axial erstreckenden Greifelementen (21), die an der Außenfläche des Mittelrohrs (3) an deren fernem Ende befestigt sind, wobei die Elemente im wesentlichen gleichmäßig um den Rand des Rohrs verteilt sind und zu einer nach außen gerichteten Erweiterung ihrer fernen Enden geeignet sind, wenn das Außenrohr (5) dem fernen Ende des Mittelrohrs (3) zurückgezogen ist, und geeignet sind, einen Spalt zwischen den Elementen (21) und dem Mittelrohr (3) zu bilden, wenn des Außenrohr (5) distal in einer axialen Richtung des Mittelrohrs (3) bewegt ist.

2. Vorrichtung zur transluminalen Implantation oder Extraktion eines im wesentlichen rohrförmigen, radial erweiterbaren Stents (27), wobei die Vorrichtung ein Mittelrohr (3) mit einem nahen und fernen Ende aufweist, das durch ein Außenrohr (5) eingefaßt ist, welches axial bezüglich des Mittelrohrs (3) verschiebbar ist, dadurch gekennzeichnet, daß das Mittelrohr (3) mit einem proximal sich erstreckenden Endabschnitt (25) an seinem fernen Ende versehen ist und der Endabschnitt (25) einen größeren Durchmesser hat als das Außenrohr (5), und eine Vielzahl von sich axial erstreckenden Greifelementen (21) an der Außenfläche des Außenrohrs (5) an dessen fernem Ende befestigt sind, wobei die Elemente (21) im wesentlichen gleich um den Rand des Rohrs (5)

verteilt sind und zu einer nach außen gerichteten Erweiterung an ihren Hinterenden geeignet sind durch axiale Vorwärtsbewegung des Mittelrohrs (3) mit seinem sich erstreckenden Endabschnitt (25), und geeignet sind zur Bildung eines Spalts zwischen den Elementen (21) und dem Außenrohr (5) durch Bewegung des Mittelrohrs (3) proximal in einer axialen Richtung des Außenrohrs (3).

3. Vorrichtung nach Anspruch 1 oder 2, ferner mit einer Griffeinrichtung (9; 11) an den Hinterenden der Rohre (3, 5), die eine axial relative Bewegung zwischen den Rohren zur Freigabe oder Faltung des Greifelemente (21) ermöglicht.

4. Vorrichtung nach Anspruch 1, 2 oder 3, wobei die Anzahl der Greifelemente (27) drei oder vier ist.

5. Vorrichtung nach Anspruch 1, wobei das Mittelrohr (3) mit radialen Öffnungen (23) an seinem fernen Ende versehen ist, die eine saubere Positionierung der Vorrichtung beim Betrieb ermöglichen.

6. Vorrichtung nach Anspruch 1, wobei das Mittelrohr (3) wenigstens an seinem fernen Ende aus einem transparenten Material gemacht ist, das eine saubere Positionierung der Vorrichtung beim Betrieb ermöglicht.

7. Vorrichtung nach Anspruch 2, wobei eines der Rohre (3, 5) mit radialen Öffnungen an seinem ferner Ende versehen ist, die eine saubere Positionierung der Vorrichtung beim Betrieb ermöglichen.

8. Vorrichtung nach Anspruch 2, wobei die Rohre (3, 5) radiale, benachbarte Öffnungen an ihren entfernten Enden haben, die eine saubere Positionierung der Vorrichtung beim Betrieb ermöglichen.

9. Vorrichtung nach Anspruch 2, wobei die Rohre (3, 5) wenigstens an ihren fernen Enden aus transparentem Material gemacht sind, das eine saubere Positionierung der Vorrichtung beim betrieb ermöglicht.

10. Vorrichtung nach einem der Ansprüche 5 bis 9, ferner mit einer Betrachtungseinrichtung, z.B. einem Endoskop oder einem Teleskop (7), das in dem Mittelrohr (3) positioniert und axial darin verschiebbar ist.

11. Vorrichtung nach einem vorhergehenden Anspruch, wobei die konzentrischen Elemente (3, 5, 7) aus flexiblen Materialien gemacht sind, die ein Biegen der Vorrichtung beim Betrieb ermöglichen.

12. Vorrichtung nach einem vorhergehenden Anspruch, wobei die Greifelemente durch vorspringende Elemente (21) gebildet sind, die bei Freigabe zu einer nach außen gerichteten Vorspringbewegung geeignet sind.

13. Kombination der Vorrichtung nach Anspruch 1 und eines im wesentlichen rohrförmigen, radial erweiterbaren Stents (27), wobei der Stent (27) zwischen den Greifelementen (21) und dem Mittelrohr (3) in einem zusammengezogenen Zustand positionierbar ist.

14. Kombination der Vorrichtung nach Anspruch 2 und eines im wesentlichen rohrförmigen, radial erweiterbaren Stents, wobei der Stent (27) zwischen den Greifelementen (21) und dem Außenrohr (5) in einem zusammengezogenen Zustand positionierbar ist.

15. Kombination nach Anspruch 13 oder 14, wobei der Stent (27) von dem selsbstdehnbaren Typ ist.

Revendications

1. Dispositif d'implantation ou d'extraction transluminale d'un dilatateur de type stent (27), sensiblement tubulaire, expansible radialement, le dispositif comprenant un tube central (3) présentant des extrémités distale et proximale, entouré par un tube extérieur (5) déplaçable axialement par rapport au tube central (3), caractérisé par une pluralité d'organes de saisie (21), s'étendant axialement, fixés à la surface extérieure dudit tube central (21), à son extrémité distale, lesdits organes étant distribués de façon pratiquement régulière sur la périphérie dudit tube et susceptibles d'une action d'expansion vers l'extérieur de leurs extrémités distales lors de la rétraction dudit tube extérieur (5) vis à vis de l'extrémité distale dudit tube central (3) et susceptibles de former un interstice entre lesdits organes (21) et le tube central (3), lorsque ledit tube extérieur (5) est éloigné dans la direction axiale dudit tube central (3).

2. Dispositif d'implantation ou d'extraction transluminale d'un dilatateur du type stent (27), sensiblement tubulaire, expansible radialement, le dispositif comprenant un tube central (3) présentant des extrémités distale et proximale, entouré par un tube extérieur (5) déplaçable axialement par rapport au tube central (3), caractérisé en ce que ledit tube central (3) est pourvu à son extrémité distale d'une section d'extrémité (25) proximale,

qui présente un diamètre supérieur à celui du tube extérieur (5), et d'une pluralité d'organes de saisie (21), s'étendant axialement, fixés à la surface extérieure dudit tube extérieur (5), à son extrémité distale, lesdits organes (21) étant distribués de façon pratiquement régulière sur la périphérie dudit tube (5) et susceptibles d'une action d'expansion vers l'extérieur à leurs extrémités arrière, par un déplacement axial de progression du tube central (3) avec sa section d'extrémité (25) déployée, et susceptibles de former un interstice entre lesdits organes (21) et ledit tube extérieur (5), par déplacement dudit tube central (3) à déplacement proximal dudit tube central (3) dans la direction axiale dudit tube extérieur (5).

3. Dispositif selon la revendication 1 ou 2, comprenant en outre un moyen servant de poignée (9,11), placé aux extrémités arrière desdits tubes (3,5), permettant d'effectuer un déplacement relatif axial entre lesdites tubes en vue de ramener ou plier lesdits moyens de saisie (21).

4. Dispositif selon la revendication 1, 2 ou 3, dans lequel le nombre d'organes de saisie (27) est de 3 ou 4.

5. Dispositif selon la revendication 1, dans lequel ledit tube central (3) est pourvu d'ouvertures radiales (23) sur son extrémité distale, permettant un positionnement correct du dispositif en fonctionnement.

6. Dispositif selon la revendication 1, dans lequel ledit tube central (3) est composé, au moins sur son extrémité distale, d'un matériau transparent, permettant un positionnement correct du dispositif en fonctionnement.

7. Dispositif selon la revendication 2, dans lequel l'un de tubes (3,5) est pourvu d'ouvertures radiales à son extrémité distale, permettant un positionnement correct du dispositif en fonctionnement.

8. Dispositif selon la revendication 2, dans lequel lesdits tubes (3,5) présentent des ouvertures radiales juxtaposées à leur extrémité distale, permettant un positionnement correct du dispositif en fonctionnement.

9. Dispositif selon la revendication 2, dans lequel lesdits tubes sont composés, à leur extrémité distale, d'un matériau transparent permettant un positionnement correct du dispositif en fonctionnement.

10. Dispositif selon l'une quelconque des revendications 5 à 9, comprenant en outre des moyens d'observation, tels qu'un endoscope ou un télescope (7), placés et déplaçables axialement à l'intérieur du tube central (3).

11. Dispositif selon l'une quelconque des revendications précédentes, dans lequel les organes concentriques (3,5,7) sont en matériaux flexibles, permettant une flexion du dispositif en fonctionnement.

12. Dispositif selon l'une quelconque des revendications précédentes, dans lequel lesdits moyens de saisie sont constitués par des organes élastiques (21), susceptibles d'assurer une action élastique vers l'extérieur une fois qu'ils sont relâchés.

13. La combinaison du dispositif selon la revendication 1 et d'un dilatateur de type stent (27), sensiblement tubulaire, expansible radialement, caractérisée en ce que ledit dilatateur de type stent (27) est susceptible d'être positionné entre lesdits organes de saisie (21) et ledit tube central (3), lorsqu'il est à l'état contracté.

14. La combinaison du dispositif selon la revendication 2 et d'un dilatateur de type stent, sensiblement tubulaire, expansible radialement, caractérisée en ce que ledit dilatateur de type stent (27) est susceptible d'être positionné entre lesdits organes de saisie (21) et ledit tube extérieur (5) est à l'état contracté.

15. La combinaison selon la revendication 13 ou 14, dans laquelle ledit dilatateur de type stent (27) est du type auto-expansible.

Fig. 1

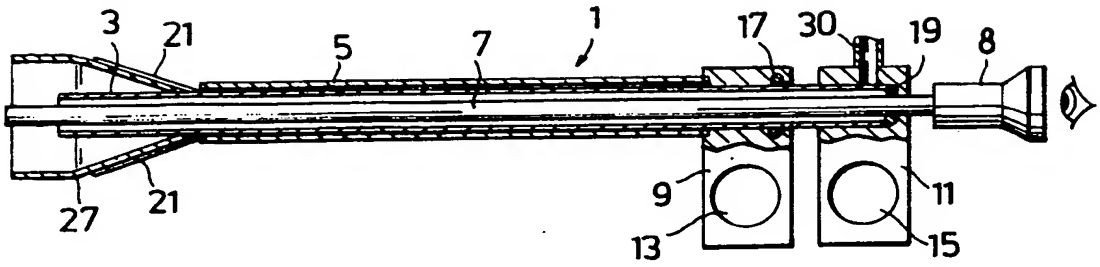


Fig. 2

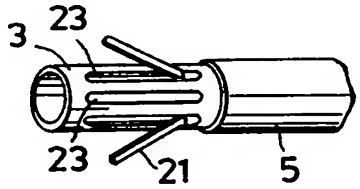


Fig. 3

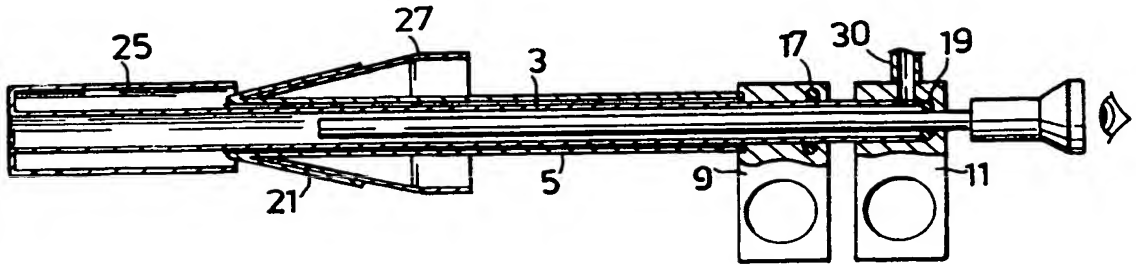


Fig. 4

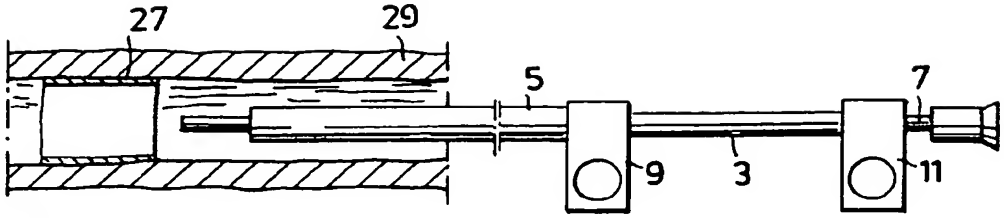


Fig. 5

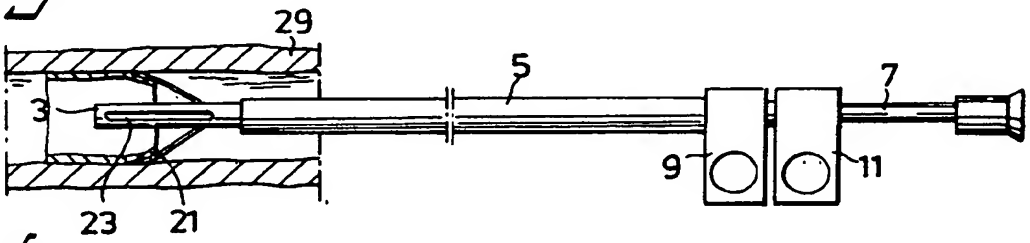


Fig. 6

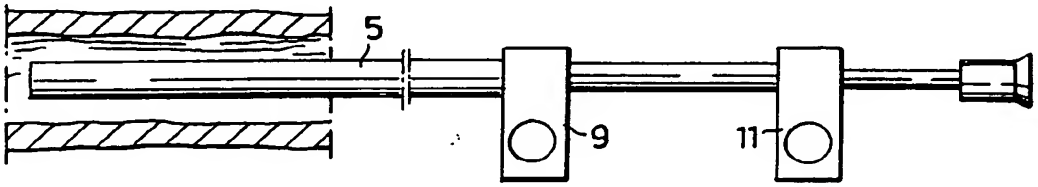


Fig. 7

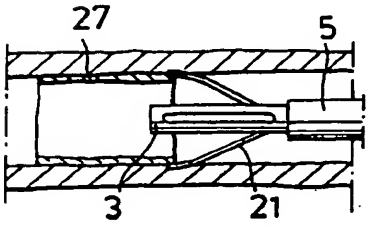
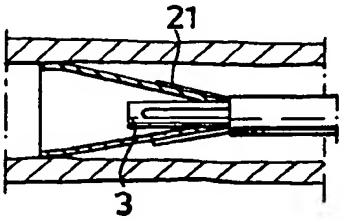


Fig. 8



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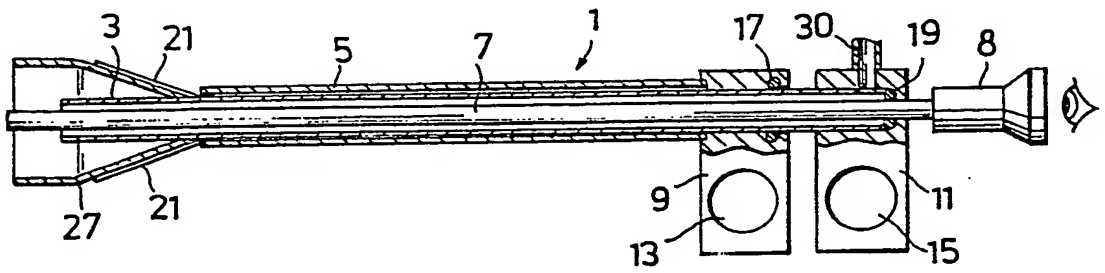
(54) A device for transluminal implantation or extraction.

(57) A device for transluminal implantation or extraction of a substantially tubular, radially selfexpanding stent (27), comprising a central tube (3) surrounded by an exterior tube (5) axially displaceable relative to the central tube (3), and a plurality of axially extending spring members (21) attached to the outer surface of said central tube (3) at the distal end thereof, said members (21) being substantially evenly distributed around the periphery of said tube (3) and capable of outward springing action of their front ends when retracting said exterior tube (5) from the distal end of said central tube (3).

Fig.1



EP 0 364 420 A1

A device for transluminal implantation or extraction.

The present invention relates to a device for transluminal implantation and/or extraction of a substantially tubular, radially expanding stent.

Devices for transluminal implantation of expanding stents or prostheses are previously known. Thus, US patent 4,732,152 describes a device enabling transluminal implantation of self-expanding stents. The device described in said US patent shows excellent performance in regard to enabling implantation of prostheses or stents in for example blood vessels or other ducts in living animal bodies. However, most implantation devices including that described in US patent 4,732,152 suffer from the serious drawback of not enabling later extraction of an implanted prosthesis or stent. Such extraction of the implanted artifact will sometimes be necessary due to improper location or disturbances created by the presence of the stent.

The present invention has for a main object to provide for an implantation device also enabling easy extraction of an implanted expanding stent when desired.

Another object of the invention is to provide for a device which can be used for implantation as well of a self-expanding stent.

Still another object of the invention is to provide a device enabling proper positioning of such self-expanding stent in connection with its implantation.

For these and other objects which will be clear from the following description the invention provides for a device comprising a central tube surrounded by an exterior tube axially displaceable relative to the central tube, and a plurality of axially extending gripping members attached to the outer surface of said central tube at the distal end thereof, said members being substantially evenly distributed around the periphery of said tube and capable of outward expanding action of their front ends when retracting said exterior tube from the distal end of said central tube. Reversely, said gripping members are capable of forming a nip between themselves and the central tube when the exterior tube is moved forward in axial direction towards the distal end of the central tube.

According to a modification of such device based on the same inventive concept said exterior tube is provided with a backwardly extended end section at the distal end of said tube, and the plurality of axially gripping members are attached to the outer surface of said exterior tube at the distal end thereof. Again, said members are substantially evenly distributed around the periphery of said exterior tube and they are capable of outward expanding action at their rear ends when said exterior tube is retracted from the annular space formed by said extended end section and the part of the interior tube surrounded by said section. Reversely, when extracting a stent, said gripping members are capable of forming a nip between themselves and said exterior tube by moving the central tube backwardly in axial direction towards the proximal end of the exterior tube. The number of gripping members is at least three and a preferred number is four, although more than four gripping members can be used.

In a preferred embodiment of the device according to the invention gripping handles are provided at the rear or proximal ends of said tubes, said means enabling axial relative movement between said tubes for expanding or folding of said spring members.

To enable proper positioning of the stent in connection with its implantation the central tube may be provided with radial openings preferably at the distal end thereof, through which the site of implantation can be inspected for the purpose of finding the correct location for the stent. It is also possible to make the central tube, at least at the distal end thereof, of a transparent material enabling such inspection.

In the modification of the device according to the invention both the central tube and the exterior tube may be provided with such radial openings at least at the distal ends thereof. Such radial openings are juxtaposed to enable proper inspection in connection with implantation. According to another embodiment said tubes are, at least at the distal ends thereof, made of transparent material to enable proper positioning. According to still another embodiment one of said tubes can be provided with radial openings at the distal end thereof, whereas the other tube can be made of a transparent material.

To enable inspection of the implantation site the device may comprise viewing means such as an endoscope or a telescope positioned inside the central tube and being axially displaceable therein.

To enable access to any location even through tortuous paths to the site of implantation the device according to the invention may be made of a flexible material including also said viewing means if present.

The invention also includes an apparatus for implanting an expandable stent, said apparatus comprising a device as defined above in combination with a stent which is positioned or clamped between said gripping members and said central tube in a contracted state. According to an alternative apparatus this combination is provided with

the stent positioned or clamped between said gripping members and said exterior tube in a contracted state. In such apparatuses the stent is preferably of the self-expanding type, and it is particularly preferred to use stents of the type described in US patent No. 4,655,771.

To facilitate the practical handling of the device of the present invention it is preferred to arrange means which prevent relative rotation between the two concentric tubes. Thus, in order to keep the preferred handles enabling axial relative movement of the concentric tubes, i.e. the central tube and the exterior tube, it is important that said handles are aligned under operation, which will be the case if said tubes are prevented from relative rotation. Such means may be constituted by members of the nut and groove type or other suitable arrangement conventional in the art to prevent such relative rotational movement.

The device according to the present invention is useful for implantation or extraction of any radially expanding ste nt, but it is particularly useful for handling stents of the type of self-expanding stents described in US patent No. 4,655,771, the full disclosure of which is incorporated herein by reference. The advantage of applying the present invention to braided stents of the type disclosed in said US patent primarily lies in the fact that when one end of such stent is subjected to radial compression at several points of its periphery the whole stent without retracting from its annular shape will contract inwardly from the location where the radial forces act. Thus, even if radial forces are applied from the outside to one end of such stent at three different positions evenly distributed around the periphery of the stent there will be no local deformations of the stent at or near said end but the stent will reduce its diameter uniformly and the radial contraction will be transmitted axially along the stent for a substantial part of its length.

The gripping members may have any shape in cross section but they could have a substantially rectangular cross section by having a blade-like shape. They may in one end be attached to the central tube 3 or the exterior tube 5, respectively, in any suitable manner, such as by welding, riveting, soldering or the like. In a preferred embodiment the gripping members are made of a blade shaped spring material and are preformed so that when released from the surrounding exterior tube respectively backwardly extended end section they spring outwardly with their free ends.

The invention will now be described by non-limiting examples with reference to the appended drawings, wherein:

Fig. 1 is a diagrammatic side view, partly in section, of an embodiment of the device of the invention;

Fig. 2 is an enlarged detail of the distal end of the device shown in Fig. 1;

Fig. 3 is a diagrammatic side view of a modification of the instrument shown in Fig. 1 enabling release or extraction of a stent in the opposite direction; and

Figs. 4 to 8 illustrate the procedure for extracting a stent implanted in the urethra of a patient.

The device shown in Fig. 1 is generally designated 1 and is principally constituted by two flexible tubes, one central tube 3 and a surrounding exterior tube 5. Said tubes are substantially coextensive except for the fact that the exterior tube 5 is shorter than central tube 3 by a distance at least corresponding to the length of the stent to be implanted. Each of tubes 3,5 is provided with gripping handles 9 and 11, respectively, attached at the rear ends thereof. Central tube 3 extends through handle 9 of the exterior tube for obvious reasons.

Central tube 3 is, at its distal end, provided with gripping members 21. The number of gripping members 21 is four and they are evenly distributed around the periphery of central tube 3. In the embodiment shown gripping members 21 have a blade-like shape and can be made of a spring steel material. They can be attached to central tube 3 by any suitable means, such as welding, riveting or other way of attachment. In a preferred embodiment of the invention members 21 are cut out of the wall of tube 3 as shown in Fig. 2 and are thus integral with the wall material of said tube. In such embodiment the tube material is suitably a metal or metal alloy having spring properties.

Gripping members 21 are capable of outward springing movement when exterior tube 5 is retracted by bringing handles 9,11 together as shown in Fig. 1. When exterior tube 5 is moved axially forward along central tube 3 spring members 21 will fold and will come to close engagement with the exterior surface of central tube 3.

The device shown in Fig. 1 further comprises a viewing device in the form of a telescope 7 placed inside central tube 3 with its viewing end 8 positioned behind handle 11. For ease of operation handles 9,11 are provided with cavities 13,15 giving a steady grip.

As seen from Fig. 2 central tube 3 is provided with openings 23 suitably positioned for a purpose to be described below.

The device shown in Fig. 1 also includes seal rings 17,19 sealing against the interior tube 3 and the telescope 7, respectively and inlet means 30, to allow a fluid such as water to be injected to the chamber between the telescope and the inner tube 3 allowing a stream of fluid to rinse the distal end of the telescope for better viewing.

The embodiment shown in Fig. 3 enables implantation and extraction of a stent from the opposite direction. In view of the construction of the stent compression thereof results in axial extension. Therefore, one end of the stent when released will obtain exact location in connection with its implantation, whereas its other end will be located in dependence on the ratio between radial contraction and axial expansion. Therefore, the embodiment of Fig. 3 may be useful when the rear end of the stent is to be correctly positioned in an exact location in a lumen.

The device shown in Fig. 3 corresponds in predominant parts to that shown in Fig 1, but the distal end of central tube 3 is provided with an outwardly and backwardly bent end section 25. Moreover, the gripping members 21 are directed rearwardly and attached to the distal end of exterior tube 5 rather than directed forwardly and attached to central tube 3 as shown in Fig. 1. In other respects the device shown in Fig. 3 corresponds closely to that shown in Fig. 1.

In the embodiment shown in Fig. 1 for loading purposes the proximal end of a stent 27 of the type described in US patent 4,655,771 is accomodated beneath gripping members 21, whereafter exterior tube 5 will be axially moved forward so as to move gripping members 21 radially inwardly to compress the proximal end of the stent 27 and keep it firmly in place in a nip against the central tube 3. By further moving the exterior tube 5 axially forward the entire stent 27 will be compressed and kept inside the exterior tube 5. When the loaded device is then inserted into the lumen of a patient, such as into a patient's urethra , not shown in Fig. 1, the telescope 7 can be axially positioned and by viewing through it the insertion can be closely inspected for establishing the proper location where stent 27 is to be released. After reaching the correct location for the distal end of the stent exterior tube 5 is moved back by handle 9. In the position shown in Fig. 1 the proximal end of the stent 27 is released from the nip between the gripping members 22 and the central tube 3. By pulling the entire device slightly backwards in relation to the urethra the entire stent is released and by moving the exterior tube 5 forwardly the gripping members 21 will fold inwardly surrounded by the protecting exterior tube 5 and the device can then be removed from the lumen, such as the urethra with the stent completely surrounded by exterior tube 5.

With regard to the embodiment shown in Fig. 3 the procedure is similar but when releasing in this case the proximal end of the stent 27 will first expand at the desired position of the vessel not shown in this figure by moving the central tube 3 axially forward and in the position shown in Fig. 3 the stent 27 is released from the nip between the gripping members 21 and the exterior tube 5. The entire device is then pushed forward in relation to the vessel lumen to completely release the stent 27, whereafter the central tube 3 is moved axially backward to the right as seen in Fig. 3 to fold gripping members 21 by the movement of end section 25 against the exterior tube 5 and thus protect the lumen from being affected by the spring members. The device can then be retracted as a whole from the lumen involved.

The procedure used for removing an implanted stent in the urethra 29 will now be described with reference to Figs. 4 to 8.

Fig. 4 shows a stent implanted into a vessel 29 of a patient, e.g. the urethra. The device used from extracting the stent from its location within the urethra is of the type shown in Fig. 1. For extracting however, the exterior tube 5 is first kept in a forward position keeping the spring members 21 in a folded position surrounded by the distal end of the tube 5 thus protecting the lumen of the vessel when moving the device. The encoscope 7 is used for locating the exact position of stent 27 as seen in Fig. 4. After reaching a position somewhat behind stent 27 exterior tube 5 is now moved backwardly, whereby spring members 21 will be released to engage the inside surface of urethra 29 with the distal ends just behind the proximal end of the stent 27. Due to the pressure exerted by spring members 21 onto the interior wall of the lumen, the device can be pushed axially forwardly as seen in Fig. 5, whereby the spring members 21 can slide onto the outside of the proximal end of stent 27. By moving exterior tube 5 to the left spring members 21 will be folded inwardly thus causing contraction of the proximal end of the stent which will be firmly kept in the nip between the spring members and the central tube 3. Further movement of exterior tube 5 to the left will bring the entire stent 27 together with spring members 21 to a position within the protecting exterior tube 5 as illustrated in Fig. 6. The device can now be removed from the urethra of the patient together with stent 27 in its contracted state.

Fig. 7 and Fig. 8 show a detail of the device according to Fig. 4. When removing a self-expanding stent as described in US patent No. 4,655,771, the spring members 21 have only to slide a very short distance, such as a few millimeters onto the interior wall of the lumen, as shown in Fig. 7. Fig. 8 shows how the end of this type of stent when contracted by the tip of the spring members will be elongated axially in direction towards the fixed ends of the spring members thus giving sufficient length of fixation in the nip between the spring members and the interior tube 3 without pushing the device forward.

Also the device of the type shown in Fig. 3 can

in a corresponding manner be used as an extractor for implanted stents.

Even if the device is described in relation to the treatment of urethras it is very suitable for the treatment of many other conduits in the human body. The same devices with optical viewing devices can be successfully used for treatments of such vessels as urethra, the trachea, oesophagus and also some blood vessels.

It is to be noted that the invention is not limited to the embodiments described herein. Thus, any suitable materials can be used for different parts of the instrument. It is preferred to use flexible materials to reach difficultly accessible locations of different types of lumen in which case also the viewing devices can be exchanged to or combined with any appropriate imaging device such as X-Ray, ultra-sound. Moreover, the invention is useful not only with regard to the type of stent described in US patent No. 4,655,771, although an excellent performance is obtained in relation to such stent.

Claims

1. A device for transluminal implantation or extraction of a substantially tubular, radially expandable stent (27), comprising a central tube (3) surrounded by an exterior tube (5) axially displaceable relative to the central tube (3), and a plurality of axially extending gripping members (21) attached to the outer surface of said central tube (3) (Fig. 1) at the distal end thereof, said members being substantially evenly distributed around the periphery of said tube and capable of outward expanding action of their distal ends when retracting said exterior tube (5) from the distal end of said central tube (3), or forming a nip between said members and the central tube (3) when said exterior tube (5) is moved forward in axial direction toward the distal end of said central tube (3).

2. A device for transluminal implantation or extraction of a substantially tubular, radially expandable stent (27), comprising a central tube (3) surrounded by an exterior tube (5) axially displaceable relative to the central tube (3), said central tube (3) being provided with a backwardly extending end section (25) at the distal end thereof, and a plurality of axially extending gripping members (21) attached to the outer surface of said exterior tube (5) at the distal end thereof, said members (21) being substantially evenly distributed around the periphery of said tube (5), and being capable of outward expanding action at their rear ends by moving the central tube (3) with its extending end section (25) axially forwardly, or forming a nip between said members (21) and said exterior tube (5) by moving said central tube (3) backwardly in axial direction toward the proximal end of said exterior tube (3)

3. A device according to claim 1 or 2, further comprising handle means (9; 11) at the rear ends of said tubes (3;5) enabling axial relative movement between said tubes for releasing or folding of said gripping members (21).

4. A device according to claim 1, 2 or 3, wherein the number of gripping members (27) is 3 or 4.

5. A device according to claim 1, wherein said central tube (3) is provided with radial openings (23) at the distal end thereof enabling proper positioning of the device under operation.

6. A device according to claim 1, wherein said central tube (3), at least at the distal end thereof, is made of a transparent material enabling proper positioning of the device under operation.

7. A device according to claim 2, wherein one of tubes (3,5) is provided with radial openings at the distal end thereof enabling proper positioning of the device under operation.

8. A device according to claim 2, wherein said tubes (3,5) have radial, juxtaposed openings at the distal end thereof enabling proper positioning of the device under operation.

9. A device according to claim 2, wherein said tubes (3,5), at least at the distal end thereof, are made of transparent material enabling proper positioning of the device under operation.

10. A device according to any of claims 5 to 9, further comprising viewing means such as an endoscope or a telescope (7) positioned inside the central tube (3) and axially displaceable therein.

11. A device according to any preceding claim, wherein the concentric members (3,5,7) are made of flexible materials enabling bending of the device under operation.

12. A device according to any preceding claim, wherein said gripping members are constituted by springing members (21) capable of outward springing action when released.

13. An apparatus for implanting a substantially tubular, radially expandable stent, comprising a device according to claim 1 in combination with such stent (27) positioned between said gripping members (21) and said central tube (3) in a contracted state.

14. An apparatus for implanting a substantially tubular, radially expandable stent, comprising a device according to claim 2 in combination with such stent (27) positioned between said gripping members (21) and said exterior tube (5) in a contracted state.

15. An apparatus according to claim 13 or 14, wherein said stent (27) is of the self-expanding type.

Fig. 1

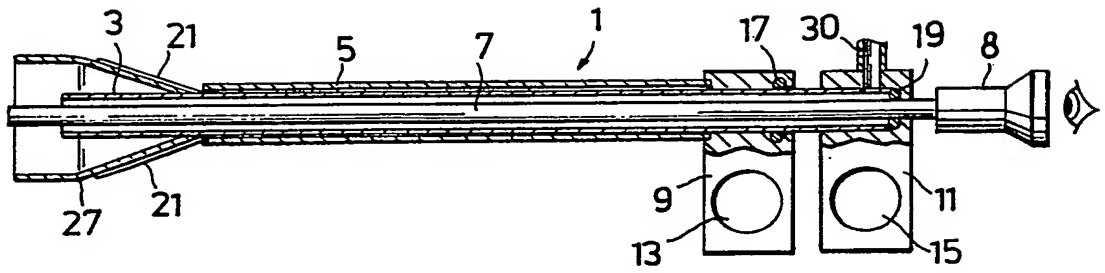


Fig. 2

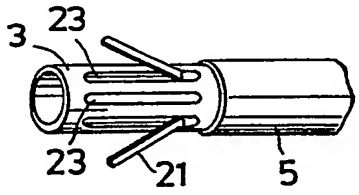


Fig. 3

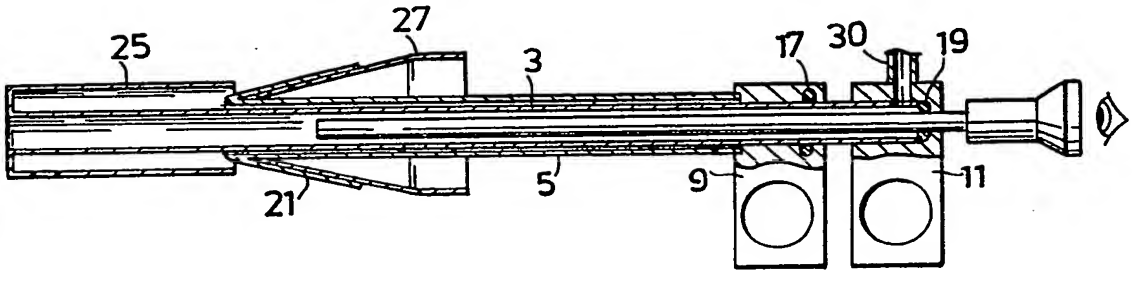


Fig. 4

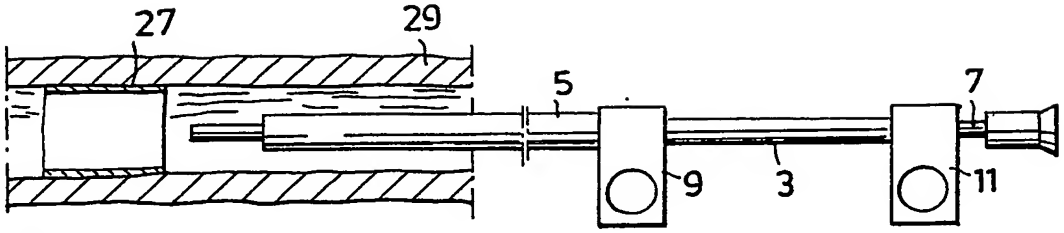


Fig. 5

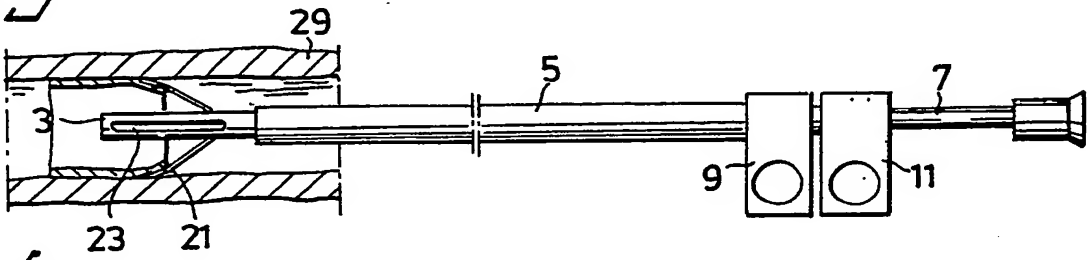


Fig. 6

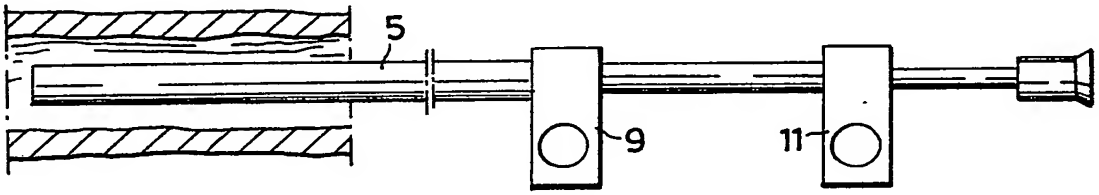


Fig. 7

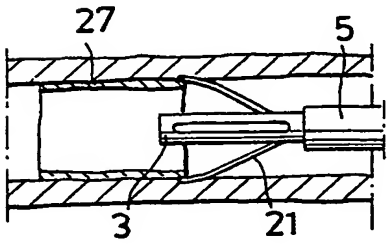
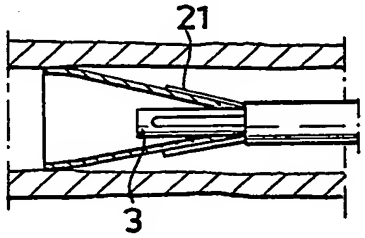


Fig. 8



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EUROPEAN SEARCH REPORT

Application number

EP 89850313.1

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.X5)
A	US - A - 4 665 918 (G.A. GARZA et al.) * Fig. 1,5,6,9a-13a; column 3, lines 1-24, 48-64; column 4, line 46-column 5, line 56 *	1,2, 13,14	A 61 M 29/00 A 61 M 25/00 A 61 F 2/04
D,A	US - A - 4 655 771 (H.I. WALLSTEN) * Fig. 5,6,11; column 5, line 60 - column 7, line 10; column 8, lines 7-48 *	1,2, 13,14	
D,A	US - A - 4 732 152 (H.I. WALLSTEN et al.) * Fig. 1,4-7; column 4, line 63 - column 5, line 64; column 6, line 23 - column 7, line 20 *	1,2, 13,14	

TECHNICAL FIELDS SEARCHED (Int. Cl.X5)
A 61 M 25/00 A 61 M 29/00 A 61 F 2/00

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
VIENNA	25-01-1990	LUDWIG

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